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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,932	07/18/2003	Subhashis Banerjee	BBI-8187RCE	3572

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
06/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,932	BANERJEE ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,10-14 and 18-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10-14 and 18-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 April 2009 has been entered.

2. Claims 1-7, 9 and 15-17 are cancelled.

Claim 35 has been amended.

3. Claims 8, 10-14 and 18-43 are pending and under consideration.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Maintained

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The rejection of claims 8, 10-14, 18-26 and 28-43 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 4/13/2009 reviews the criteria for establishing a *prima facie* case of obviousness, with which the examiner takes no issue. The response states that the obvious to try rationale relied upon does not adequately establish a *prima facie* case of obviousness. Applicant argues that Oh et al teaches the treatment of psoriasis with infliximab (chimeric TNFα antibody) as successful and provides a dramatic improvement and Oh et al does not refer to the treatment as short-term or limited in efficacy as characterized by the examiner (citing pg. 7 of the previous Office Action, 1/13/09). Applicant is critical and alleges that the examiner has failed to establish the recognized problem or need in the art raised by Oh et al, as Oh et al teaches successful treatment of psoriasis. Applicant states that the examiner seems to be taking contradictory positions regarding the teachings of Oh et al, relying upon Oh et al for providing the motivation in that the reference teaches a need for better treatment of psoriasis ("in view of the limited and short-term efficacy of infliximab as taught by Oh et al"), and for teaching a reasonable expectation of success ("in view of the teachings of Oh et al, providing evidence that the administration of an anti-TNFα antibody is clinically effective for psoriasis"). Applicant questions how a single reference can teach both a "clinically effective" treatment for psoriasis and "limited and short-term efficacy". Applicants' arguments have been fully considered but are

not found persuasive. Regarding the teachings of Oh et al, applicant's reply filed 4/14/08 acknowledges that "This reference further mentions that the patient's improvement was gradually lost (i.e., the patients PASI scores returned to baseline), and that a second intravenous infusion of 5 mg/kg of the antibody 16 weeks after the first infusion resulted in a similar course of clinical improvement of the patient's psoriasis." (bottom of pg. 10 of the reply) and "The reference further reports that the patient's clinical progress gradually returned to baseline for both diseases after 16 weeks, at which time the patient received a second intravenous infusion of 5 mg/kg and demonstrated a similar course of clinical improvement." (reply filed 11/3/08 at pg. 10). Applicant now argues and acknowledges that Oh et al teaches the treatment of psoriasis with infliximab as successful and provides a dramatic improvement and asserts that Oh et al does not refer to the treatment as short-term or limited in efficacy as characterized by the examiner. Thus, applicants' criticism is curious in view that applicant originally advanced the position that the treatment of Oh et al only provides an improvement that is gradually lost (i.e., limited and short-term efficacy), yet applicant now agrees with the basis of the original rejection in that Oh et al teach that the treatment of psoriasis with an anti-TNFα antibody (infliximab) as successful and providing a dramatic improvement. Further, with respect to the alleged contradictory position of the examiner regarding the teachings of Oh et al, the instant rejection is based on the motivation to modify the teachings of Oh et al using the human TNFα antibody of Salfeld et al and Keystone et al in the treatment of psoriasis and the reasonable expectation of success that the treatment would provide some therapeutic benefit in psoriasis patients. Thus, the instant rejection does not rely upon the need for the treatment of psoriasis as motivation, since Oh et al already teach the successful treatment of psoriasis in a patient using an anti-TNFα antibody. The appropriate question is whether one of ordinary skill in the art would have been motivated to use the fully human anti-human TNFα antibodies and antigen-binding fragments thereof of Salfeld et al [a] and Keystone et al in the treatment of psoriasis as taught by Oh et al.

It is reiterated that as set forth in the original rejection and reiterated in subsequent Office Actions, one of ordinary skill in the art would have been motivated to modify the method of Oh et al using the human anti-human TNFα antibodies and antigen-binding fragments thereof of Salfeld et al [a] (i.e., identical to the claimed antibodies) in order to avoid any unwanted

immune reaction in human patients due to the presence of murine sequences in the chimeric anti-TNFα antibody (infliximab) of Oh et al. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983).

Regarding applicants' assertion as to "clinical efficacy" being inconsistent with the "limited and short-term efficacy" of Oh et al, applicant is reminded obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). There is nothing inconsistent with the fact that Oh et al teaches the successful treatment of psoriasis with a TNFα antibody and while the beneficial effects may not be long-lasting or the best therapy, this does not overcome the fact that Oh et al does teach that the anti-TNFα antibody treatment was successful and provided a dramatic improvement in psoriasis patients as acknowledged by applicant. Clinical efficacy or complete disease resolution is not the standard.

Thus, consistent with MPEP 2143(E), the teachings of Oh et al provide an effective therapy for treating psoriasis using an anti-TNFα antibody, thereby establishing a recognized problem or need in the art and a predictable potential solution to the recognized need or problem and one of ordinary skill in the art could have pursued the known subcutaneous biweekly administration of the known fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al at 20 mg, 40 mg and 80 mg for the treatment of psoriasis, since the teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Again, "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397.

Applicants' arguments at pp. 11-12 of the reply filed 4/13/2009 are acknowledged, but are not found persuasive. The idea that one of ordinary skill in the art would not modify the

teachings of Oh et al since Oh et al teaches the successful treatment of psoriasis makes little sense since the prior art teaches that because chimeric and humanized antibodies still retain some of murine sequence, they still may elicit an unwanted immune reaction in human patients. Thus one of ordinary skill in the art would have been motivated to use the D2E7 fully human TNFα antibody of Salfeld et al [a] and Keystone et al (identical to the claimed antibodies) in order to avoid any unwanted immune reaction in human psoriasis patients due to the presence of murine sequences in the chimeric anti-TNFα antibody of Oh et al.

Further, since one of ordinary skill in the art would have been led to the D2E7 fully human TNFα antibody of Salfeld et al [a] and Keystone et al, it also makes little sense that one of ordinary skill in the art would follow the dosing regimen for infliximab when using the D2E7 fully human TNFα antibody, particularly in view that the subcutaneous biweekly administration of the D2E7 fully human anti-TNFα antibody at 20 mg, 40 mg and 80 mg was known to be well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, common sense and ordinary skill would have led the ordinary skilled artisan to follow a known dosing regimen for the antibody to be used in the therapy (e.g., D2E7), rather than follow the dosing regimen for a different antibody (e.g., infliximab) and which might be affected by unwanted immune reaction in human patients.

Applicant again presents that different dosing regimens for the chimeric TNFα antibody, infliximab, used for treatment of psoriasis and rheumatoid arthritis to support the position that the same agent to treat more than one disorder does not necessarily have the same dosing regimen. Applicant concludes that one of average skill in the art would not have reasonable expectation of success in applying the teachings of rheumatoid arthritis described in Keystone et al to psoriasis and applicant argues that Salfeld et al [a] similar to Oh et al teaches weight based doses rather than a fixed body dose, i.e., a dose that is the same throughout. Applicants' arguments have been fully considered but are not found persuasive. While Keystone et al do teach the subcutaneous biweekly administration of the fully human anti-TNFα antibody D2E7 as taught by Salfeld et al [a] at 20 mg, 40 mg and 80 mg for the treatment of *rheumatoid arthritis*, the teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, while one of

ordinary skill in the art would recognize that the optimal dosing regimen for the D2E7 antibody may vary for the treatment of other TNFα-mediated disorders, such as psoriasis as taught by Oh et al, given the success of D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly), one of ordinary skill in the art would have been motivated to at least administer the D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week for the treatment of psoriasis. "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. Additionally, applicant is reminded that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Salfeld also teaches that "[d]osage regimens may be adjusted to provide the optimum desired response (e.g., a therapeutic or prophylactic response). For example, a single bolus may be administered, several divided doses may be administered over time or the dose may be proportionally reduced or increased as indicated by the exigencies of the therapeutic situation… It is to be further understood that for any particular subject, specific dosage regimens should be adjusted over time according to the individual need and the professional judgment of the person administering or supervising the administration of the compositions, and that dosage ranges set forth herein are exemplary only and are not intended to limit the scope or practice of the claimed composition (see pp. 33-34). Thus, according to the teaching of Salfeld, *the dosage regimen for anti-TNFα antibody, including dosage scheduling and amount, is a recognized results-effective variable,* i.e., a variable that is recognized as important for therapeutic use of an anti-TNFα antibody and which therefore can be optimized by routine experimentation. See M.P.E.P. § 2144.05 II.B. and *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

7. The rejection of claims 8, 10-14, 18-26 and 28-43 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) in view of Salfeld et al [b] (US Patent 6,509,015 B1, 2/9/1996, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 4/13/2009 argues as above and the examiner's remarks above apply here as well and are incorporated herein by reference. It is noted that the instant rejection differs only in the use of Salfeld et al [b], however, Salfeld et al [a] and [b] are equivalent teachings.

Therefore, as discussed supra the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

8. Claims 8, 10, 12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) and Neuner et al (Photochem Photobiol., 59(2):182-188, Feb 1994).

The response filed 4/13/2009 argues as above and states that the teachings of Neuner et al do not make up for the deficiencies in Oh et al, Salfeld et al [a] and Keystone et al. Applicants' arguments have been fully considered but are not found persuasive. The examiner's remarks above apply here as well and are incorporated herein by reference.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. The provisional rejection of claims 8, 10-14, 18-26 and 28-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-10, 16-21, 78-79, 81, 84, 86-88, 95, 97-98 and 100-104 of copending Application No. 10/163,657 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 4/13/2009 states that the rejection is provisional in nature and will be addressed when appropriate, i.e., when the nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP 804 I.B.). Applicants' remarks are acknowledged, however, in view that the claims are rejected on other grounds and not presently in condition for allowance, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/163,657, discussed above, would form the basis for a rejection of the noted claims under 35

U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

11. The provisional rejection of claims 8, 10-14, 18-25 and 28-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 9-22, 25-26 and 28-53 of copending Application No. 11/104,117 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 4/13/2009 states that the rejection is provisional in nature and will be addressed when appropriate, i.e., when the nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP 804 I.B.). Applicants' remarks are acknowledged, however, in view that the claims are rejected on other grounds and not presently in condition for allowance, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/104,117, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly

owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. The provisional rejection of claims 8, 10-14, 18-26 and 28-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 11/233,252 (***allowed, not yet issued***) in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 4/13/2009 states that the rejection is provisional in nature and will be addressed when appropriate, i.e., when the nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP 804 I.B.). Applicants' remarks are acknowledged, however, in view that the claims are rejected on other grounds and not presently in condition for allowance, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/233,252, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35

U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

13. The rejection of claims 8, 10-14, 18-25 and 28-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 36-39 and 69-70 of U.S. Patent No. 6,509,015 B1 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-8892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 4/13/2009 argues as above, i.e., the combined teachings of Salfeld et al, Oh et al and Keystone et al fail to provide a reasonable expectation of success for the treatment of psoriasis with biweekly, subcutaneous dosage regimen of human anti-TNFα antibody as presently claimed. Applicants' arguments have been fully considered but are not found persuasive for the reasons set forth above and incorporated herein by reference, and in view that no terminal disclaimer has been filed.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application

was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

14. No claim is allowed.

15. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with

alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643